



May 20, 2021

Possis Medical, Inc.
Mark Stenoien
Director Of Regulatory Affairs
9055 Evergreen Blvd., N.w.
Minneapolis, Minnesota 55433-8003

Re: K082382

Trade/Device Name: AngioJet Ultra AVX Thrombectomy Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Mark Stenoien:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 12, 2008. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'Connell -S

Digitally signed by
Gregory W. O'Connell -S
Date: 2021.05.20
09:34:46 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2008

Possis Medical, Inc.
c/o Mr. Mark D. Stenoien
Director of Regulatory Affairs
9055 Evergreen Boulevard, N.W.
Coon Rapids, MN 55433

Re: K082382
AngioJet® Ultra AVX® Thrombectomy Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: November 20, 2008
Received: November 21, 2008

Dear Mr. Stenoien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

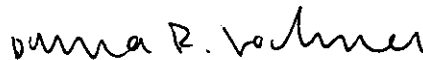
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082382

Device Name: AngioJet® Ultra AVX® Thrombectomy Set

Indications For Use: The AngioJet Ultra AVX Thrombectomy Set is intended for use with the AngioJet Ultra System in breaking apart and removing thrombus from A-V access conduits ≥ 3 mm in diameter.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
NEEDED)

Suma R. Vachani
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082382

K082382

5. 510(k) Summary

DEC 12 2008

Submitter: Possis Medical, Inc.
9055 Evergreen Boulevard, N.W.
Coon Rapids, MN 55433

Contact Person: Mark D. Stenoien
Director Regulatory Affairs
Phone: 763.717.1092
Fax: 763.780.2227
Email: mark.stenoien@possis.com

Device Common Name: Embolectomy Catheter

Device Trade Name: AngioJet® Ultra AVX® Thrombectomy Set

Device Classification Name: Embolectomy Catheter

Predicate Devices: AngioJet Ultra AVX Thrombectomy Set (K073441)

Device Description

Each AngioJet Ultra AVX Thrombectomy Set is a sterile, single use, disposable set that includes the AngioJet AVX Thrombectomy catheter and pump in one combined unit. The AngioJet Ultra AVX Thrombectomy Set is used with the AngioJet Ultra Console. A 3-port catheter manifold is used, so that contrast media and other fluids can be injected into the vascular where the catheter is positioned.

Indications for Use

The AngioJet Ultra AVX Thrombectomy Set is intended for use with the AngioJet Ultra System in breaking apart and removing thrombus from A-V access conduits ≥ 3 mm in diameter.

Comparison to Predicate Devices

Possis Medical, Inc. considers the AngioJet Ultra AVX Thrombectomy Set to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.

Supporting Information

Bench and biocompatibility testing supported using a 3-port catheter manifold and adding labeling instructions for using the AngioJet Ultra AVX Thrombectomy Set to inject contrast media and other fluids into the vascular site where the catheter is positioned.